

### **REMARKS**

Claims 1 – 19 are pending in the application. Claims 4 – 6, 10, 13 and 14 have been cancelled. Claims 1, 7, 8 and 11 have been amended.

No new matter has been added by virtue of these amendments; support therefore can be found in throughout the specification and original claims of the application. Specifically, support for the amendment. The amendments find support in claims 6 and 10 obviating the need for an RCE for further consideration. Also the amendments find support in the specification, for example at paragraphs [0100], [0105] – [0109].

Any cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

#### **Claim Rejections Withdrawn**

The rejection of claim 7 under 35 USC 112, second paragraph, by the Examiner has been withdrawn.

#### **Rejection of Claim 11 under 35 U.S.C. 112, second paragraph**

The Examiner has rejected Claim 11 under 35 USC 112, second paragraph as being indefinite. Specifically, the Examiner is of the opinion that "the instant claim, as written, is indefinite with regard to the term 'a DNA fragment obtained by substitution or deletion of a part of the base constituting the DNA fragment.'" (Office Action, p.3). Applicants respectfully traverse the rejection.

Applicants have amended instant Claim 11 to recite "substitution or deletion of one to several bases." This language clarifies that the substitution is of one or several bases, not a part of an individual base. Base substitution or deletion is supported in the specification, for example at paragraphs [0105] – [0109] of Example 9. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

**Rejection of Claims 1 – 3, 6 – 7, 11 – 12 and 15 - 19 under 35 U.S.C. 102(b)**

**Claims 1 – 3, 6 – 7, 11 – 12 and 15 - 19 stand rejected under 35 U.S.C. §102(b) over Boele et al. (US Patent 5,536,661).** Applicants respectfully traverse the rejection.

Claim 1 recites a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including CGGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter, wherein the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, and wherein the modified promoter is capable of functioning in a filamentous fungus.

To anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure § 2131:

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”  
Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Boele et al. reference does not teach or suggest all the limitations of the instant claims. In particular, the Boele et al. reference does not teach or suggest a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including GGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter, **wherein the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter**, according to the instant claims. The instant specification teaches enhanced promoter activity observed when inserting a

first and second DNA fragment as a pair, as compared to a single fragment or a plurality of fragments. For example, paragraphs [0099] and [0100] of the published application teach that

enhancing the promoter activity by singly inserting CCAAT sequence or SRE was not observed...on the other hand, in the modified promoter (PSCP) in which a CCAAT sequence and SRE were inserted at the same time, as compared with the wild type promoter (taap), significant increase in the activity was observed, and about 4 times amylase activity was observed. From the results, it can be said that **in order to increase the promoter activity, it is important to insert both CCAAT sequence and SRE at the same time.** (emphasis added).

The Examiner argues that “Boele et al teaches construction of a vector comprising a ‘TAKA-amylase promoter or functional parts thereof’ for expression of a protein in *Aspergillus* (and) further teaches wherein the promoter contains a first base sequence ‘CCAATTAGAAG’ and a second base sequence ‘CGGAAATTTAAAGG’ that are arranged sequentially from the 5’ end side to the 3’ end side of said promoter.” (Office Action, p.5). However, nowhere does Boele et al. teach a modified promoter, where the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5’ end to the 3’ end side of said promoter, and where, as shown in the instant specification, insertion as a pair increases promoter activity. The Boele et al. reference simply teaches a promoter and upstream activating sequences suitable for expression of a protein product (see, e.g. claims), where the inserted promoter is preceded by its upstream activating sequences.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

#### **Rejection of Claims 7 - 10 under 35 U.S.C. 102(b)**

**Claims 7 – 10, and 16 stand rejected under 35 U.S.C. §102(b) over Minetoki et al. (Appl. Microbiol Biotechnol 1998).** Applicants respectfully traverse the rejection.

Claim 7 is dependent on claim 1, and recites the modified promoter according to claim 1, wherein said first DNA fragment and said second DNA fragment are inserted at the 5'-end side that is upstream to a CCAAT sequence existing in said promoter or at the 3'-end side that is downstream to a SRE sequence existing in the promoter region.

As discussed above, to anticipate a claim, each and every element of the claim must be found in a single reference. The Minetoki et al. reference does not teach or suggest all the limitations of the instant claims. In particular, the Minetoki et al. reference does not teach or suggest a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including GGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter, **wherein the first DNA fragment and the second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter,** according to the instant claims. Again, Applicants direct the Examiner to the examples in the instant application, set forth above, that show the enhanced promoter activity observed when inserting a first and second DNA fragment as a pair, as compared to a single fragment or a plurality of fragments.

The Examiner argues that Minetoki et al. teaches "modification of the promoter for the *Aspergillus oryzae* amyB gene (and) teach inserting multiple copies of region IIIa sequence which contains the first DNA fragment including the "CCAATNNNN" sequence into the promoter region of a modified vector." (Office Action, p.9). However, the Minetoki et al. reference merely teaches introducing multiple copies of the fragment comprising region III into the *Aspergillus* promoter (see, e.g. p.460, p.461, col. 1, p.464 col. 1). Nowhere does the Minetoki reference expressly or inherently teach or suggest the first DNA fragment and the second DNA fragment that are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that they are arranged sequentially from the 5' end to the 3' end side of said promoter, as instantly claimed.

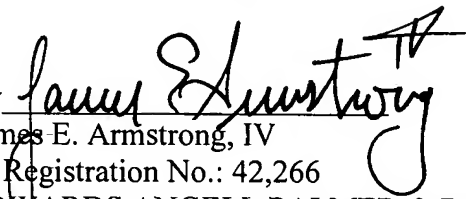
Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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